

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ORION CORPORATION,

Plaintiff/Counterclaim  
Defendant,

v.

WOCKHARDT USA, INC.  
and WOCKHARDT LIMITED,

Defendants/Counterclaim  
Plaintiffs.

CIVIL ACTION NO. 07-550 (GMS)

**ANSWER TO COUNTERCLAIMS**

Orion Corporation ("Orion"), for its Answer to the counterclaims of Wockhardt Limited ("Wockhardt"), states as follows:

**Nature of the Action**

1. Orion admits that Wockhardt purports to assert counterclaims for a declaration of patent noninfringement and invalidity arising under the Declaratory Judgment Act, 28 U.S.C. §2201 *et seq.*, and the patent laws of the United States, 35 U.S.C. §1 *et seq.*, but denies that any of those counterclaims are valid or sustainable.
2. Orion admits that subject matter jurisdiction is proper under 28 U.S.C. §§1331 and 1338(a). Orion denies any remaining averments of paragraph 2.
3. Orion admits that this Court has personal jurisdiction over Orion in this matter. Orion denies any remaining averments of paragraph 3.

4. Orion admits that venue is proper in this judicial district for the purpose of this matter.
5. Orion admits that there is an actual and justiciable case or controversy concerning Orion's United States Patent Nos. 5,446,194 ("the '194 patent") and 5,135,950 ("the '950 patent"). Orion denies any remaining averments of paragraph 5.

### **The Parties**

6. Upon information and belief, Orion admits the averments of paragraph 6.
7. Upon information and belief, Orion admits the averments of paragraph 7.
8. Orion admits that Orion is a corporation organized and existing under the laws of Finland and has a principal or regular and established place of business at Orionintie 1, FI-02200 Espoo, Finland. Orion denies that "Orion is engaged in the business of manufacturing, marketing, and distributing pharmaceutical products around the world."

### **The Patents and Related Drug Product**

9. Orion admits that, pursuant to 21 U.S.C. §355(j), "any person may file with the Secretary an abbreviated application for the approval of a new drug..." which, *inter alia*, has the same active ingredient as that of a listed drug and is bioequivalent to the listed drug. Orion denies any remaining averments of paragraph 9.

10. Orion admits that, pursuant to 21 U.S.C. §355(b), the NDA “applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” And “upon approval of the application, the Secretary shall publish information submitted...” Orion denies any remaining averments of paragraph 10.

11. Orion admits that 21 U.S.C. §355(j)(2)(A)(vii)(IV) requires “a certification...with respect to each patent which claims the listed drug...or which claims a use for such listed drug for which the [ANDA] applicant is seeking approval under this subsection...that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted.” Orion denies any remaining averments of paragraph 11.

12. Orion admits that, pursuant to 21 U.S.C. §355(j)(2)(B)(iv), a notice of opinion that a patent is invalid or will not be infringed must “state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification” and “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Orion denies any remaining averments of paragraph 12.

13. Orion admits that, pursuant to 21 U.S.C. §355(j)(5)(B)(iii), if “an action...for infringement of the patent that is the subject of the certification...” is brought “before the expiration of 45 days after the date on which the notice [under] paragraph (2)(B) is received,” an applicant’s ANDA will not be approved until “the expiration of the thirty-month period beginning on the date of the receipt of the notice...or such shorter or longer period as the court may order...” or until the patent infringement action is resolved in favor of the ANDA applicant. Orion denies any remaining averments of paragraph 13.

14. Orion admits the averments of paragraph 14.

15. Orion admits the averments of paragraph 15.

16. Orion admits that the ‘194 patent, the ‘950 patent and United States Patent No. 6,599,530 (“the ‘530 patent”) are listed in the Orange Book entry for Comtan, NDA No. 20-796. Orion denies any remaining averments of paragraph 16.

17. Upon information and belief, Orion admits that Wockhardt submitted ANDA No. 78-941 to the FDA to obtain approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Wockhardt’s proposed entacapone 200 mg tablets before the expiration of the ‘194, ‘530, and ‘950 patents. Orion denies that the ‘194, ‘530 and ‘950 patents are invalid or unenforceable. Orion denies that the ‘194 and ‘950 patents will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of Wockhardt’s proposed entacapone 200 mg tablets. Orion lacks knowledge or information

sufficient to form a belief as to the truth of any remaining averments of paragraph 17 and, therefore, denies the same.

18. Upon information and belief, Orion admits the averments of paragraph 18.

19. Orion admits that, on September 13, 2007, Orion filed a Complaint against Wockhardt and Wockhardt USA, Inc. (collectively "Defendants") for infringement of and declaratory judgment in favor of the '194 and '950 patents. Orion admits that Orion asserted in its Complaint, and continues to assert, that under 35 U.S.C. §271(e)(2)(A), Defendants infringed one or more claims of the '194 and '950 patents by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '194 and '950 patents, of entacapone 200 mg tablets, a product the manufacture, importation, use or sale of which would infringe one or more claims of the '194 and '950 patents. Orion denies any remaining averments of paragraph 19.

20. Orion admits that a Stock Exchange Release, dated September 13, 2007, stated that Orion "has filed a patent infringement lawsuit in the United States to enforce U.S. Patent No. 5,446,194 and U.S. Patent No. 5,135,950 against generic drug companies Wockhardt USA, Inc. and Wockhardt Limited, who seek to market generic entacapone (200 mg tablets) in the United States," and that "Orion Corporation and Novartis will vigorously defend the intellectual property rights covering Comtan." Orion denies any remaining averments of paragraph 20.

21. Orion admits that a Stock Exchange Release, dated September 13, 2007, stated that Orion "has filed a patent infringement lawsuit in the United States to enforce

U.S. Patent No. 5,446,194 and U.S. Patent No. 5,135,950 against generic drug companies Wockhardt USA, Inc. and Wockhardt Limited, who seek to market generic entacapone (200 mg tablets) in the United States,” and that “Orion Corporation and Novartis will vigorously defend the intellectual property rights covering Comtan.” Orion denies any remaining averments of paragraph 21.

22. Orion admits that Orion has a publicly accessible website at [www.orion.fi](http://www.orion.fi). Orion admits that the [www.orion.fi](http://www.orion.fi) website, under the “Research and product development risks” section, states that “in developing its products Orion endeavours to protect them efficiently and over a wide area, whilst defending the rights of its products diligently both by itself and together with its marketing partners.” Orion denies any remaining averments of paragraph 22.

23. Orion admits that Orion has not sued Wockhardt for infringement of the ‘530 patent. Orion admits that the ‘530 patent is listed in the Orange Book entry for Comtan, NDA No. 20-796. Orion admits that Orion stated in a Stock Exchange Release, dated September 13, 2007, that “Orion Corporation and Novartis will vigorously defend the intellectual property rights covering Comtan.” Orion lacks knowledge or information sufficient to form a belief as to the truth of any remaining averments of paragraph 23 and, therefore, denies the same.

24. Orion denies the averments of paragraph 24.

25. Orion denies the averments of paragraph 25.

### **Counterclaim Count I**

26. Orion repeats and incorporates by reference its responses to paragraphs 1-25 as if fully set forth herein.
27. Orion admits that Wockhardt, in counterclaim count I, seeks a declaratory judgment of noninfringement of each claim of the '194 patent. Orion denies that the manufacture, use, importation, offer for sale, and/or sale of Wockhardt's proposed entacapone 200 mg tablets for treatment of Parkinson's disease will not infringe at least one claim of the '194 patent.
28. Orion admits that an actual and justiciable case or controversy exists between Orion and Wockhardt concerning the infringement of the '194 patent. Orion denies any remaining averments of paragraph 28.
29. Orion denies the averments of paragraph 29.
30. Orion denies the averments of paragraph 30.

### **Counterclaim Count II**

31. Orion repeats and incorporates by reference its responses to paragraphs 1-25 as if fully set forth herein.
32. Orion admits that Wockhardt, in counterclaim count II, seeks a declaratory judgment of invalidity of each claim of the '194 patent. Orion denies that the manufacture, use, importation, offer for sale, and/or sale of Wockhardt's

proposed entacapone 200 mg tablets for treatment of Parkinson's disease will not infringe at least one valid claim of the '194 patent.

33. Orion admits that Wockhardt, in counterclaim count II, states that an actual and justiciable case or controversy exists between Orion and Wockhardt concerning the invalidity of the '194 patent. Orion denies any remaining averments of paragraph 33.

34. Orion denies the averments of paragraph 34.

### **Counterclaim Count III**

35. Orion repeats and incorporates by reference its responses to paragraphs 1-25 as if fully set forth herein.

36. Orion admits that Wockhardt, in counterclaim count III, seeks a declaratory judgment of noninfringement of each claim of the '950 patent. Orion denies that the manufacture, use, importation, offer for sale, and/or sale of Wockhardt's proposed entacapone 200 mg tablets for treatment of Parkinson's disease will not infringe at least one claim of the '950 patent.

37. Orion admits that an actual and justiciable case or controversy exists between Orion and Wockhardt concerning the infringement of the '950 patent. Orion denies any remaining averments of paragraph 37.

38. Orion denies the averments of paragraph 38.

39. Orion denies the averments of paragraph 39.



#### **Counterclaim Count IV**

40. Orion repeats and incorporates by reference its responses to paragraphs 1-25 as if fully set forth herein.
41. Orion admits that Wockhardt, in counterclaim count IV, seeks a declaratory judgment of invalidity of each claim of the '950 patent. Orion denies that the manufacture, use, importation, offer for sale, and/or sale of Wockhardt's proposed entacapone 200 mg tablets for treatment of Parkinson's disease will not infringe at least one valid claim of the '950 patent.
42. Orion admits that Wockhardt, in counterclaim count IV, states that an actual and justiciable case or controversy exists between Orion and Wockhardt concerning the invalidity of the '950 patent. Orion denies any remaining averments of paragraph 42.
43. Orion denies the averments of paragraph 43.

#### **Counterclaim Count V**

44. Orion repeats and incorporates by reference its responses to paragraphs 1-25 as if fully set forth herein.
45. Orion admits that Wockhardt, in counterclaim count V, seeks a declaratory judgment of noninfringement of each claim of the '530 patent. Orion lacks knowledge or information sufficient to form a belief as to the truth of any remaining averments of paragraph 45 and, therefore, denies the same.

46. Orion admits that Orion filed a Complaint asserting only the '194 and '950 patents. Orion admits that Wockhardt's submission of ANDA No. 78-941 included a Paragraph IV Certification regarding the '530 patent. Orion denies any remaining averments of paragraph 46.

47. Orion lacks knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 47 and, therefore, denies the same.

48. Orion lacks knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 48 and, therefore, denies the same.

#### **Counterclaim Count VI**

49. Orion repeats and incorporates by reference its responses to paragraphs 1-25 as if fully set forth herein.

50. Orion admits that Wockhardt, in counterclaim count VI, seeks a declaratory judgment of invalidity of each claim of the '530 patent. Orion lacks knowledge or information sufficient to form a belief as to the truth of any remaining averments of paragraph 50 and, therefore, denies the same.

51. Orion admits that Orion filed a Complaint asserting only the '194 and '950 patents. Orion admits that Wockhardt's submission of ANDA No. 78-941 included a Paragraph IV Certification regarding the '530 patent. Orion denies any remaining averments of paragraph 51.

52. Orion denies the averments of paragraph 52.

53. Orion denies that Wockhardt is entitled to the relief requested in its Prayer for Relief, or to any other relief.

**PRAYER FOR RELIEF**

WHEREFORE, Orion respectfully requests this Court to enter judgment against Wockhardt as follows:

- (a) dismissing each of Wockhardt's counterclaims with prejudice;
- (b) finding that this is an exceptional case and granting Orion reasonable attorney fees pursuant to 35 U.S.C. § 285; and
- (c) awarding Orion any further and additional relief as this Court deems just and proper.

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